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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,758	03/24/2004	Daniel J. Von Seggern	5410-006 (312552-24)	6593
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DLA PIPER LLP (US) 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			EXAMINER BLUMEL, BENJAMIN P	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 02/20/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/808,758	<b>Applicant(s)</b> SEGGERN, DANIEL J. VON	
	<b>Examiner</b> BENJAMIN P. BLUMEL	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on July 2, 2008 & November 7, 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14-16 and 18-48 is/are pending in the application.
- 4a) Of the above claim(s) 5, 18-22, 29-33 and 41-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10, 14-16, 23-28 and 34-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/24/04, 10/12/04, 12/21/04 & 2/10/05.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of invention I and the required species in the replies filed on July 2, 2008 and November 7, 2008 is acknowledged. The traversal is on the ground(s) that searching what effect a specific modification has on the fiber protein relating to adenovirus serotype 37 would include relevant art pertaining to all effects such a modification would cause since the search is based on the same serotype (Ad37). Therefore, the search of one serotype does not pose a serious search burden. In response, while the claimed serotypes of subgroup D share some level of common structure, a search for Ad37 fibers would not encompass all of the subgroup D serotype fibers because they each possess a level of heterogeneity.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5, 18-22, 29-33 and 41-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 2, 2008 and November 7, 2008.

Claims 1-4, 6-10, 14-16, 23-28 and 34-40 are examined on the merits.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 9/24/04, 10/12/04, 12/21/04 & 2/10/05 were filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/459,000 and/or the foreign priority document PCT/US03/02295 fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Provisional application '000 and foreign priority document fail to teach or suggest any aspect of targeting dendritic cells or the comparison of one chimeric fiber bearing adenovirus to a native fiber bearing adenovirus with regard to dendritic cell interaction. Therefore, claims 1-4, 6-10, 14-16, 23, 24, 26-28 and 34-40 are only supported by the provisional application 60/467,500. As a result, the earliest priority date of the instant invention is that of May 1, 2003. In addition, the specification of the foreign priority document fails to support that limitation in claim 25 that requires that the fiber protein of Ad37 causes a reduced interaction with HSP. Therefore, the earliest priority date for claim 25 is that of provisional 60/459,000 (i.e., March 28, 2003).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 7, 9, 10, 16, 23, 24 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites, "...wherein the fiber is modified to reduce any interaction with...(HSP).", however, it is unclear if the modification claimed is the act of making a chimeric fiber protein as recited in claim 1 or if additional steps have been taken to reduce any interaction with HSP (i.e., what has been done to the fiber to have this affect on HSP).

Claim 7 recites the limitation "the capsid" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 9 and 10 recite, "...amino acids set forth as SEQ ID NO: 31...", however, it is unclear which amino acids this is referring to since SEQ ID NO: 31 is a nucleic acid sequence.

Claim 15 recites the limitation "the capsid" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites, "...replacing the N-terminal 15, 16 or 17 amino acids with the 15, 16 or 17 amino acids of an Ad5 fiber.", however, it is unclear if the amino acids replaced are from amino acid 1 to 15, 1 to 16 or 1 to 17 of the N-terminus or the 15th, 16th or 17th N-terminal amino acid. Furthermore, it is also unclear where in the Ad5 fiber protein that these replacement amino acids are coming from.

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Claim 23 recites the limitation "the genome thereof" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 24 is rejected since it depends from claim 23.

Claim 28 recites, "A composition of claim 26 that is a vaccine.", however it is unclear what this vaccine is directed towards since no additional limitations are claimed. The metes and bounds of the claims cannot be determined without further clarification.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8, 14, 25-27 and 34-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Shankara (WO 99/47180) and Huang et al. (Journal of Virology, 1999).

The claimed invention is drawn to an adenovirus particle with a heterologous fiber or a portion thereof, whereby binding of the viral particle to dendritic cells is increased compared to a particle that expresses native fiber proteins. The adenovirus particle is Ad5 adenovirus (a subgroup C adenovirus) with the fiber comprising a sufficient portion from adenovirus 37 (a subgroup D adenovirus) that targets dendritic cells. The fiber can be chimeric with the N-terminus portion from a subgroup C adenovirus which is sufficient to increase incorporation into the particle in comparison to its absence in the fiber protein; or the fiber is wholly from Ad37 which imparts a reduced interaction with HSP. The recombinant adenovirus particle is formulated for

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administration via intramuscular, IV or parenteral routes. The claimed invention also includes an adenovirus vector that encodes this recombinant adenovirus particle, which includes heterologous nucleic acids and dendritic cells that contain these nucleic acid molecules.

Shankara teaches the generation of a recombinant Ad2 (a subgroup C adenovirus) with a heterologous fiber protein or a chimeric fiber protein with heterologous portions from Ad17 (a subgroup D adenovirus). Shankara teaches that upon replacing all of the Ad2 fiber protein except for the first 16 N-terminal amino acids with the complementing regions of Ad17 fiber proteins, dendritic cell targeting increased greater than 10 fold. (Table 2). As a result, Shankara suggests that the fiber of subgroup D adenoviruses permits the targeting of dendritic cells. Shankara also teaches the development of recombinant Adenovirus 5 with a heterologous fiber protein from Adenovirus 2. Shankara also suggests that recombinant adenoviruses can be formulated in such a way to facilitate administration via intramuscular routes. However, Shankara does not teach the use of Ad37 fiber protein segments; or the lack of HSP interaction by the recombinant adenovirus. *See pages 6, 7, 26.*

Huang et al. teach the generation of recombinant Ad37 fiber proteins for determining how amino acid mutations can alter the cellular tropism of the fiber protein. *See pages 2798 and 2799.*

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Shankara in order to create a recombinant Ad5 with a fiber protein containing either all or a portion of the fiber protein from Ad37, thereby targeting dendritic cells and generating a recombinant adenovirus with a fiber protein that has a



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reduced interaction with HSP. One would have been motivated to do so, given the suggestion by Shankara that Ad2 (a C adenovirus) with a fiber protein from Ad17 (a D adenovirus) increases the targeting of dendritic cells. There would have been a reasonable expectation of success that the Ad37 (a subgroup D adenovirus) fiber protein substitution would have resulted in increased targeting of dendritic cells, given that Shankara teaches that the fiber protein of subgroup D adenoviruses permits the targeting of dendritic cells. Although Shankara and Huang et al. do not comment on reduced HSP interaction, this would have been a natural outcome of combining their teachings as outlined above. The structure of the product is the same as is instantly claimed, thus any function(s) associated with the claimed structure is expected to be present in the structure of the prior art. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/  
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/  
Examiner  
Art Unit 1648